

**UNIT STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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13

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/080,666	03/27/01	ROBERT M. MCKEE	13-1000-00001

09/080,666
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EXAMINER

MR. R. L. P.

ART UNIT	PAPER NUMBER
13-1000	5

DATE MAILED:

04/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/525,998	Applicant(s) Hauptmann et al.
	Examiner Prema Mertz	Group Art Unit 1646

Responsive to communication(s) filed on Oct 24, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-26 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Notice of Comply with Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 22-23, drawn to a DNA molecule encoding a TNF receptor protein, a host cell, and a method of making the TNF receptor protein, classified in Class 435, subclass 69.1.

II. Claims 19-21, 24, drawn to a TNF receptor protein, classified in Class 530, subclass 350.

III. Claim 25, drawn to a method of treatment with a TNF receptor protein, classified in Class 514, subclass 2.

IV. Claim 26, drawn to a method of detection of TNF in a biological sample by using a TNF receptor protein, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of invention I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of invention II can be used as a probe, or used therapeutically or diagnostically, e.g. in screening.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used

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to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions II and III-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention I can also be used as an antigen in the production of antibodies.

Inventions I and II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III-IV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search

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(see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37 CAR 1.821(d) which requires a copy of the "Sequence Listing" in computer readable form (CRF) be submitted in accordance with 37 CAR 1.824. Alternatively, the following paragraph, or language having the same effect, can be used to invoke the procedures of 37 C.F.R. § 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

The computer readable form of the "Sequence Listing" in this application, 09/525,998, is identical with that filed in Application Number 08/383,676, filed 2/1/95. In accordance with 37 C.F.R. § 1.821(e), please use the [first-filed, last-filed or only-filed, which ever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary

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change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the "Sequence Listing" is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 28, 2001